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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

PONNALURI, PADMASHRI

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/726,624

Applicant(s)

LI, MIN

Examiner

Padmashri Ponnaluri

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,5,9,17,45-51,53-63 and 65-75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5,9,17,45-51,53,55,56,58-65,67,68 and 70-75 is/are rejected.
- 7) ☒ Claim(s) 54,57,66 and 69 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/12/05 has been entered.
2. Claims 1, 5, 9, 17, 22, 45-51, 53-63, 65-75 are currently pending and are being examined in this application. Claims 1, 5, 9, 17, 22 have been amended by the amendment filed on 12/16/04.
3. The new matter rejection and the lack of written description rejection of record has been withdrawn in view of applicants amendments and response filed on 12/16/04.
4. The art rejections over Schatz et al and Brabas et al for the reasons of record have been withdrawn in view of amendments to the claims.

### ***Priority***

5. This application is a divisional of 08/861,572, which claims priority to provisional application 60/018,074 filed on 5/22/96.

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Art Unit: 1639

7. Claims 1, 5, 9, 17, 45-51, 53, 55-56, 58-65, 67-68, 70-72 are rejected under 35

U.S.C. 102(e) as being anticipated by US Patent 5,627,024 (Maruyama et al) (filing date 8/5/94).

The instant claims briefly recite methods for detecting the presence of a polypeptide in a sample by contacting the sample with a population of recombinant virus expressing the ligand for the polypeptide on the surface, and detecting the binding of the virus to the sample, and thus detecting the presence of the polypeptide.

Maruyama et al teach lambdoid bacteriophage vectors for expression and display of foreign proteins. The reference teaches that the phage library screening can be utilized to enrich the library for one or more particles expressing a multimer having a preselected substrate or ligand binding specificity. The reference further teaches that the phage library is a population of particles enriched for a preselected ligand binding specificity (refers to instant claim limitation 'each virus expressing on its surface the ligand for the polypeptide') (i.e., see column 30). The reference teaches that the phage library comprises a population of particles, and hundreds of fusion proteins on the particle surface (refers to instant claim 'at least 10 copies of ligand', 'at least 100 copies of ligand', and 'at least 400 copies of ligand') depending on growth conditions and other factors (i.e., see column 30). The reference teaches that the library of phage (monovalent phage) having the pV-derived membrane anchor will typically contain 1-4 copies of the ligand-binding complex on the surface of each particle, and a library of phage (polyvalent phage) having the pD-derived membrane anchor will typically contain 20-420 copies of the ligand-binding complex on the surface of each particle (refers to instant claim 'at least 10 copies of ligand', 'at least 100 copies of ligand', and 'at least 400 copies of ligand') (i.e., see column 15). The reference teaches that the population of phage express the same multimer on the particle

Art Unit: 1639

surface and such phage are homogeneous and clonally derived, and therefore provide a source for expressing large quantities of a particular fusion protein (i.e., see column 30).

The reference teaches various methods that would utilize the biological activity of the fusion protein of the interest, for example to detect the presence, and preferably the amount of a preselected receptor (refers to instant claims 'selected polypeptide') ligand or enzyme with which the fusion protein binds to or reacts (i.e., see column 45). The assay can be conducted on a sample using fusion protein or phage displaying the fusion protein (refers to virus expressing on its surface) of the invention as a reagent (i.e., see column 45). The reference teaches method of labeling the fusion proteins or the phage particles of the invention (refers to 'detectable virus' of the instant claims) (i.e., see column 45). The reference teaches that the target material may be detected by the fusion protein of the instant invention when present in a sample of biological fluids and tissues (refers to the instant claim 'sample').

The reference teaches the method of detecting the presence of preselected target (selected polypeptide) in a sample comprising: a) admixing the sample containing the preselected target with the recombinant lambdoid bacteriophage of the invention, wherein the preselected target is a biologically active ligand or receptor (refers to instant claim 'cellular protein'); the lambdoid bacteriophage forms a complex with the preselected target; and detecting the presence of the complex thereby the presence of the preselected target (i.e., see column 46, claim 19). The reference teaches that the phage of the invention can be labeled when used in a diagnostic method of the invention (i.e., see column 8). The reference teaches that the sample can be blood, plasma, serum, tissue extract, body fluid sample (i.e., see column 47). Thus, the reference clearly anticipates the claimed invention.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1, 5, 9, 17, 45-51, 53, 55-56, 58-65, 67-68, 70-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,627,024 (Maruyama et al) and US Patent 5,922,545 (Mattheakis et al).

Maruyama et al has been discussed supra. The instant claims differ from the prior art teachings of Maruyama et al by reciting the 'virus is a filamentous bacteriophage; and 'coat protein pVIII.'

Maruyama et al teach the use of the lambdoid bacteriophage (lytic phage) in the method of detecting the presence of the polypeptide in the sample. Maruyama et al do not teach the filamentous phage particle library, wherein the coat protein is pVIII. However, Mattheakis et al teach improved methods and novel compositions for identifying peptides and single chain antibodies that bind to predetermined receptors or epitopes. The reference teaches methods of screening of bacteriophage peptide display library. The reference teaches fusion proteins composed of a antibody (vH and vL subunits) linked to the amino-terminus of filamentous bacteriophage coat protein typically pIII or pVIII. Thus, it would have been obvious to one skilled in the art at the time the invention was made to use filamentous phage coat protein pVIII instead of lambdoid phage taught by Maruyama et al, because the filamentous phage have more advantages, i.e. , the filamentous phage do not kill the host, and extrude progeny phage from the

Art Unit: 1639

cell. A person skilled in the art would have been motivated to use the filamentous phage to display proteins of interest because the filamentous phage would not kill the host and the phage is used in subsequent rounds of recombination.

***Allowable Subject Matter***

10. Claims 54, 57, 66 and 69 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. The following is a statement of reasons for the indication of allowable subject matter: The method of selecting polypeptides in the sample using N-methyl D-aspartate receptor, and ligands of the sequence SEQ I DNO: 2 or 3 is neither taught nor suggested by the prior art.

***Response to Arguments***

12. Applicant's arguments with respect to claims 1, 5, 9, 17, 45-51, 53, 55-56, 58-65, 67-68, 70-75 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner is on Increased Flex Schedule and can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

Art Unit: 1639

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Padmashri Ponnaluri  
Primary Examiner  
Art Unit 1639

23 June 2005



**PADMASHRI PONNALURI**  
**PRIMARY EXAMINER**